ACRO
ASSOCIATION OF CLINICAL RESEARCH ORGANIZATIONS

March 4, 2022

Dear Members of the Healthy Futures Task Force,

Thank you for the opportunity to comment on the Modernization Subcommittee's RFI regarding wearable technologies, telemedicine, and healthcare modernization. The Association of Clinical Research Organizations (ACRO) is made up of the world's leading clinical research organizations and technology providers. Our member companies are hired by sponsor companies to execute their clinical trials and are currently involved in the majority of clinical trials in the United States and around the world. ACRO members provide an array of specialized services across the entire spectrum of drug, biologic, and medical device development—from discovery, pre-clinical, proof of concept, and first-in-man studies, through post-approval and pharmacovigilance research.

We have reviewed the Subcommittee's RFI and believe our members have valuable insights that serve the goals of the RFI. Please find feedback from our members below.

Question	**Answer**
Have you used wearable technologies to facilitate the collection of data as part of a clinical trial?	Yes, ACRO members have used multiple wearable technologies to facilitate the collection of data as a part of clinical trials for more than 5 years.

If so, what have been the benefits and the challenges to collecting data using wearable technology as part of a clinical trial?	**Benefits to collecting data using wearable technologies:**
	• The number of site visits for patients and the time taken at the site during each visit can have a degree of flexibility
	• Remote disease/event management burden is reduced during the execution of clinical trial
	• Continuous physiological data collection compared to point in time data collection leads to greater insights into the medical condition of each subject which improves care
	  ○ Provides access to easily collectable quantitative measures (e.g., Parkinson's tremor tracking)
	  ○ Quantitative data can be coupled with qualitative patient-reported outcomes (PROs) to give a comprehensive overview of the patient experience

	○ Provides an opportunity for novel disease and treatment clinical insights which are made available through continuous monitoring, which may lead to earlier diagnosis, intervention, and better outcomes • Data anomaly-related notification and alerting can be provided in near real time leading to timely intervention, which helps physicians to act before a major emergency arises • Reduces subjectivity and rater bias • Can create a natural history of a given disease, which creates a better baseline for evaluating the effect of disease modifying therapies **Challenges of collecting data using wearable technologies:** • Device selection can be tricky based on subject populations (e.g., pediatric vs. geriatric) and geographies where complex import/export regulations need to be taken into consideration • Subject training and compliance can be a challenge and can lead to inadequate quality and quantity of data • Device selection based on intended use of the data becomes more nuanced – many wearable devices can generate a number of endpoints but understanding the regulatory approval per endpoint and intended use can be challenging • Limited direction/clarity on how to use the huge amount of data that is gathered due to the evolving nature of the technology and limited volume of data available for research • Limited single platforms which are device agnostic to integrate with multiple devices and gather data all at one place • Data integration and aggregation is a challenge when multiple devices are used in a single patient – correlation and synchronization of data can be a challenge • Device companies are often small and do not have the clinical trial regulatory understanding or may have not designed the device to include the controls expected for clinical trials (21 CFR Part 11 for instance)

	• Newer, emerging technology companies often do not have the data security models and company structure in place to support larger trials • Validation studies and device comparison are expensive, though we are seeing more pharma companies supporting them to select their future devices
Have you considered the use of wearable technology to collect data as part of a clinical trial but refrained because of regulatory barriers or uncertainty? If so, please provide details.	ACRO members have seen hesitancy from many clients due to the traditional and risk-averse nature of the industry. Wearable technologies can be seen to overcomplicate studies. That, coupled with the fact that most regulations in this area are newer, can lead to a perceived increased risk. Complexities also arise due to the global nature of the clinical research industry. With global studies import regulations, medical device approvals per region and local data storage needs can become complex. If a study is being run exclusively in the United States, this becomes much simpler. Clarity is needed in terms of how device companies "apply for use in clinical trials." Before using a device to collect primary or secondary endpoints for a study, the approval of the device as a *medical* device with approved specific endpoints needs to be considered, which adds a layer of uncertainty. Many of the devices create raw data which then is processed using sophisticated algorithms to create meaningful endpoint-derived data and the management of complex software in endpoint generation is still maturing. Due to the uncertainty, devices are often used in *addition* to traditional endpoints. This is considered an additional expense for the trial under consideration.
Does FDA's regulatory framework sufficiently allow for the use of data generated from wearable technologies to support findings in	Progress has been made on this front, as the FDA has started providing guidance on this topic. A possible suggestion for improvement might be to provide more clarity, particularly in terms of regulatory expectations for incorporating digital health technology and devices in trials.

clinical studies?	
What are some opportunities for and barriers to development of new wearable technologies?	Clarity and support for the measures that can be used to replace traditional endpoints would be helpful. Fast track approval of medical devices for intended use is one of the biggest opportunities but is also a barrier to development and implementation of new wearable technologies. Further supporting “software as a medical device” approaches for algorithms intended to add more insight
What steps have been taken to ensure patients’ data gathered from wearable devices is secure?	Qualification of device suppliers, review of processes and IT security, patient de-identification, system access controls, and data archive security are all steps ACRO members take to ensure the security of patient data gathered from wearable devices. ACRO members have implemented regulatory compliant device agnostic platforms for data collection with capabilities to deidentify the subjects during the trial. If data flow needs to include a vendor cloud, teams ensure that the vendor is approved for the intended use and has the appropriate data security in place. Demographic data collected at source is limited to the details that are mandatory. Subjects are identified only using the protocol subject ID code. Access to the platform is restricted to authorized personnel who need access as per the role that they play in the clinical trial.
What challenges to ensuring the security of patients’ data gathered from wearable devices persist?	External circumstances such as cyberattacks leading to unauthorized access to data persist. Additionally, apps and platforms are often designed for commercial use and therefore need further development to operate in a clinical trial setting.
What is Congress’ role in ensuring patients’ data remains secure?	Congress should continue to require the necessary regulatory controls and guidelines for conduct of clinical trials with measures as well as emphasis on patient’s data security. Requirements for device companies to maintain data security and PHI anonymization, ensuring that data for clinical trial use is portioned separately and not able to be used for other purposes, unless the participant consents for

	secondary use of de-identified data, is extremely important.

Thank you again for the opportunity to provide feedback on this important initiative. ACRO and its members stand ready to assist you in developing policy informed by the clinical research, data, and technology expertise that ACRO members possess. Please do not hesitate to contact us if you need more information or would like to discuss any of our above comments further.

Sincerely,

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